

Tennessee Medical Laboratory Board  
July 20, 2018  
Minutes

Meeting Date: July 20, 2018

Time: 9:00 AM CDT

Location: Tennessee Department of Health  
Division of Health Licensure and Regulations  
Metro Center Complex, Iris Room, Ground Floor  
665 Mainstream Drive  
Nashville, TN 37243

Members Present:

Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Dir., Chair  
Keisha Burnett, S.A.-Cytotechnologist  
Mark A. Calarco, DO, Independent Lab Manager/Adm.  
Tereyo M. Cox, MT-Medical-Technologist, General  
Carla M. Davis, MD-Pathologist  
Stephanie Dolsen, MT Supervisor  
Kathleen Kenwright, Ed.D MT- Med. Technologist,  
Educator  
Michael Johnson, MT-Medical Technologist Generalist  
Board Vice-chair  
Gaye G. Jolly, MT-Hospital Administrator  
Jon Parham, DO Non-Pathologist Physician

Members Absent:

Jason S. Nolan, MD-Pathologist, Non-Educator

Vacant Position:

Pathologist Educator  
Citizen Representative

Staff Present:

Lynda S. England, MT Consultant, Director  
Nina V. Smith, MT Consultant Administrative Office  
Kyonzte Hughes-Toombs, Deputy General OGC  
Julia Daniels, MT Consultant/Surveyor ETRO  
Taylor Carpenter, MT Consultant/Surveyor ETRO  
Richard Carroll, MT Consultant/Surveyor MTRO  
Susan Wilson, MT Consultant/Surveyor MTRO  
Karon Hathcoat, MT Consultant/Surveyor WTRO  
Debbie Haggard, MT Consultant/Surveyor WTRO

Staff Absent:

Mary Hamblen, MT Consultant/Surveyor

CLIA Manager/Representative:

Sandra Bogard, MT CLIA Manager

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| Presiding Officer:   | Patti Walton, MT, Chair  |
| Call To Order:   | The meeting was called to order at 9:14 am CDT by Board Chair Patti J. Walton.   |
| Introduction of Board Members/Staff:                             | Board members and staff made their introductions to the audience and for the record.   |
| Quorum:  | Ten board members were present which constitute a quorum.  |
| Approve Minutes  |  |
| P & E Committee Meeting  | A motion to approve the April 18, 2018 Personnel & Education Committee minutes was made by Mr. Johnson.<br>Second: Dr. Calarco.<br>Minutes: Approved.  |
| Full Board Meeting   | A motion to approve the April 19, 2018 board minutes was made by Ms. Jolly.<br>Second: Ms. Dolsen.<br>Board Minutes: Approved  |
| Board Reports:   |  |
| Ratification of Initial Determinations<br>P&E Committee Meeting: | Ms. Kenwright reported the actions of the Personnel & Education Committee meeting, July 19, 2018.<br>Motion to ratify Committee actions: Mr. Johnson.<br>Second: Dr. Calarco.<br>Report: Accepted as presented by Ms. Kenwright. |
| Consent, Agreed<br>Compliance Orders<br>Letters of Reprimand     |  |
| Consent Orders   | No consent orders presented.   |
| Agreed Orders  | No Agreed Orders presented.  |
| Compliance Orders  | No Compliance Orders presented.  |
| Letters of Reprimand   | No Letters of Reprimand presented.   |
| Presentations to the Board:                                      |  |

Tennessee Professional Peer Assistance  
Program  
(TNPAP):

Mr. Mike Harkreader, MS,RN,CARN  
TNPAP Director

The statistical report for July 1, 2017-June 30, 2018  
was presented by Mr. Harkreader.  
Two individuals were monitored during this time period.

One individual was referred for a substance abuse  
disorder while the other individual was referred from  
a treatment facility and declined services; no practice  
act violations here.

One individual declined TnPAP services and was  
referred to the Dept. of Health's Bureau of  
Investigations for the Department of Health Licensure  
& Regulation for board director and advisory attorney  
review.

Motion to accept the TNPAP report: Ms. Dolsen.  
Second: Ms. Kenwright.  
Report accepted as given.

Note: Review of TnPAP materials via internet counts as  
clock hours toward continuing education credits.  
A certificate of completion documenting review of  
these materials can be completed at the end of the  
session. Internet site: [www.TNPAP.org](http://www.TNPAP.org)

Financial Report  
Noranda M. French  
Presentation/Discussion

Ms. French gave the Mid-Year 2018 Fiscal report during  
the April meeting to include expenditures and  
projections for the fiscal year. Those expenditures are  
comparable with those of 2017 year end data.  
A revised report will be presented to board members  
during their October meeting.

No board action taken on this matter.

A copy of the report is on file in the administrative  
office.

Investigations Report  
Lori L. Leonard  
Disciplinary Coordinator  
October 2017-December 2017

Ms. Leonard's investigative report included the following:

**Monitored Practitioners:**

Four suspensions, one probation, two currently under board order, one TSAC suspension (will be removed per new legislation 2018 session).

**Investigative Licensed Laboratory Personnel:**

Three new complaints; one drug allegation; one for unprofessional conduct, the third for malpractice. Two complaints closed one sent on to OGC for CE violation another closed with letter of concern.

**Investigative Licensed Facilities:**

Two new complaints: One for malpractice and second for nonlicensed practice.

**Motion To Accept Report:** Ms. Dolsen.

Second: Mr. Johnson.

The investigations report was accepted as given.

Legislative Report  
DOH Commissioner's Office  
Patrick F. Powell, JD  
Legislative Liaison  
Legislative Affairs

Mr. Powell presented the following information promulgated by the legislature during their 2018 session relative to medical laboratory board oversight. This information is provided in the form of public chapters:

**Legislative Update - 2018**

**Public Chapter 611**

This law requires an agency holding a public hearing as part of its rulemaking process, to make copies of the rule available in "redline form" to people attending the hearing.

**Effective: July 1, 2018.**

#### **Public Chapter 744**

This statute allows a licensing entity the discretion to not suspend/deny/revoke a license in cases where the licensee has defaulted or become delinquent on student loans if a medical hardship significantly contributed to the default or delinquency.

**Effective: January 1, 2019.**

#### **Public Chapter 745 and Public Chapter 793**

These public chapters work together to create and implement the “Fresh Start Act.” Licensing authorities are prohibited from denying an application or renewal for a license/certificate/registration due to a prior criminal conviction that does not directly relate to the applicable occupation.

Lays out the requirements on the licensing authorities as well as the exceptions to the law (ex: rebuttable presumption regarding A and B level felonies).

**Effective: July 1, 2018.**

#### **Public Chapter 754**

This chapter prevents any board, commission, committee, etc. created by statute from promulgating rules, issuing statements, or issuing intra-agency memoranda that infringe on an entity member’s freedom of speech.

Freedom of speech includes, but is not limited to, a member’s freedom to express an opinion concerning any matter relating to that governmental entity, excluding matters deemed to be confidential under TCA 10-7-504.

Violations as determined by a joint evaluation committee may result in recommendations to the general assembly concerning the entity’s sunset status, rulemaking authority and funding.

**Effective: April 18, 2018.**

#### **Public Chapter 788**

This chapter is the department of health (TDH) administration bill “Medlab.” This exempts public health lab personnel employed by TDH from the licensure requirements of the Tennessee Medical Laboratory Act. This is intended to open up a greater pool of qualified candidates for open lab positions.

**Effective: April 20, 2018.**

### **Public Chapter 929**

This act redefines policy and rule and requires each agency to submit a list of all policies, with certain exceptions, that have been adopted or changed in the previous year to the chairs of the government operations committees on July 1 of each year. The submission shall include a summary of the policy and the justification for adopting a policy instead of a rule. This act also prohibits any policy or rule by any agency that infringes upon an agency member's freedom of speech.

Finally, this act establishes that an agency's appointing authority shall have the sole power to remove a member from a board, committee, etc.

**Effective: July 1, 2018 and applies to policies adopted on or after that date.**

### **Public Chapter 954**

This legislation requires the initial licensure fee for low-income persons to be waived.

Low income individuals per the statute are defined as persons who are enrolled in a state or federal public assistance program including but not limited to TANF, Medicaid, and SNAP.

All licensing authorities are required to promulgate rules to effectuate the purposes of this act.

Effective: January 1, 2019.

### **Public Chapter 1021**

This act allows for appeals of contested case hearings to be in the chancery court nearest the residence of the person contesting the agency action or at that person's discretion, in the chancery court nearest the place the action arose, or in the chancery court of Davidson County. Petitions seeking review must be filed within 60 days after entry of the agency's final order.

**Effective: July 1, 2018.**

Several licensed health professionals serving as board members expressed their concern as individuals with Public Chapter 788 in having non-clinical trained personnel employed in state public health laboratories considering the specificity/complexity of the tests performed in those locations.

No further discussion on this legislative update.

Motion to accept the report: Dr. Calarco.

Second: Ms. Cox.

Report accepted as given.

Discuss, review, take action,  
if needed:

Advisgroup  
Mokena, IL 60448  
Region One Health  
Memphis, TN

During the April 2018 meeting board members were unable provide a response based on the information given during the presentation relative to the necessity of licensure for this Region One Health location, and requested Ms. Hughes-Toombs to perform additional research with the facility and return with her findings.

Kyonzté Hughes-Toombs, JD  
Deputy General Counsel,  
Office of General Counsel  
Board Advisory Attorney

Research status:

Advisory Counsel, Ms. Hughes-Toombs reported concerning a conversation with the Region One Health administration concerning the operations of the Shelby County Healthcare Corporation d/b/a Region One relating to a change of ownership (CHOW) and the possibility of state licensure for this clinical facility per Rules and Regulations 120006-03-.16 (2) (a-c).

After this review, it was determined a state license was not required relative to the parameters defined within that conversation, and related the operations to be defined as a physician's office laboratory based on the testing performed to be only on the patients of that physician's group with no referral testing performed for non-group physicians or their patients.

After the report, board members agreed with the advisory attorney's findings and no further action was taken on this matter.

Point of Care Exemptions  
1200-06-03-.16(1)

1. Marsh Regional Blood Center  
111 West Stone Drive #300  
Kingsport, TN 37660  
Jean E. Reece MPH MTASCP) SC  
Marsh Quality Specialist

Request for non-licensed personnel to inoculate specimens into sample-bottles for bacterial contamination in leuko-platelet and platelet apheresis products relating to change in test methodology.

Original request granted in 2004; however change in methodology and instrument to BacT/Alert #3D is requested this time.

Motion: Ms. Dolsen.  
Second: Mr. Johnson.  
Exemption request: Approved.

2. Holston Valley Medical Center  
130 W. Ravine Road  
Kingsport, TN 37660  
LaDonna Compton, MT(ASCP)  
Lead POCT Coordinator

This point of care exemption request was granted to permit Certified Registered Nurse Anesthetists (CRNA's) to perform and report hematocrit, and potassium analyses in the Operating Rooms/OR's in the medical center utilizing i-STAT instrument and methodology.

Motion: Dr. Calarco.  
Second: Dr. Parham.  
Exemption granted.

3. Parkridge East Hospital  
941 Spring Creek Road  
Chattanooga, TN 37412  
Helen Richardson, MT  
Administrative Director

Board members granted this point of care exemption to permit licensed Registered Nurses to perform and report lactate and creatinine analyses in the Emergency Center utilizing the EPOC system.

Motion: Mr. Johnson.  
Second: Dr. Calarco.  
Exemption granted.

Direct 3+ Labs  
1200-06-03-.13(5)

Henry D. Edwards, MD  
Department of Pathology  
St. Thomas Midtown Hospital  
Nashville, TN 37336

Dr. Edwards appeared before the board to request approval for the directorship of his fifth laboratory.

He currently serves as medical laboratory director for the following Tennessee licensed facilities:

- 1-LabPlus, St. Thomas River Park Hospital-McMinnville.
- 2-LabPlus, St. Thomas Highlands Hospital-Sparta.
- 3-LabPlus, St. Thomas Dekalb Hospital-Smithville.
- 4-LabPlus, St. Thomas Stones River Hospital-Woodbury.

The hospital in Woodbury is adding point of care testing operations and a second license is necessary for those out-of-laboratory tests. (POC)

Dr. Edwards is requesting to be director of operations for that additional license because he is already on site for the clinical laboratory operations of the clinical laboratory under the direction/ownership of the LabPlus corporation.

The point of care activities are not under the umbrella of the LabPlus corporation.

Motion: Ms. Jolly.  
Second: Dr. Parham.  
Abstain: Dr. Davis.

Directorship of 5<sup>th</sup> laboratory approved.

Reports/Requests  
Board Director's Report  
Lynda S. England BS MT(ASCP)

The report included statistical data concerning the licensure of laboratory personnel, facilities, training programs licensure and health fair/health screening events.

Motion to approve report as given: Mr. Johnson.  
Second: Ms. Dolsen.  
Report accepted as given.

A copy of this report is kept on file in the administrative office.

Board Attorney Report  
Kyonzté Hughes-Toombs  
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:

One open case is currently the Office of General Counsel. The re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are getting closer to rulemaking event.

Red-lined rules will be sent to med lab director for review then on to rulemaking possibly during October meeting.

Motion to accept report as given: Mr. Johnson.  
Second: Dr. Parham.  
Report accepted as given.

#### Reinstatement of License

No licenses were presented for reinstatement this quarter.

#### Additions/Deletions Board's Waived Test List

No requests for additions or deletions presented during this meeting.

#### Licensure of Medical Laboratory Director

Zenjun Lou, Ph.D.  
Alpharetta, GA 30004

Dr. Lou received his BS degree in biochemistry from Jilin University, China in 1992 and his Ph.D. from Michigan State University in East Lansing, MI in 2004 with completion of the studies in Biochemistry and Molecular Biology.

His post-doctoral training was completed at the University of Texas Southwestern Department of Cell Biology from 2004-2009 in Cell Biology, Molecular Biology and Biochemistry.

Dr. Lou's fellowship was completed at the University of Texas Southwestern Department of Pathology in Clinical Cytogenetics 2009-2011.

The applicant is currently boarded by the American Board of Medical Genetics and Genomics (ABMGG) in Clinical Cytogenetics and Genomics.

He is also currently boarded by the American Board of Bioanalysis (ABB) in the specialty of Molecular Diagnostics.

Director Clinical Cytogenetics:  
Motion: Ms. Jolly.  
Second: Dr. Davis.  
License Approved.

Director Molecular Diagnostics:  
Motion: Ms. Kenwright.  
Second: Mr. Johnson.  
License Approved.

Regional Surveyors Reports:  
Complaint Investigations  
Proficiency Testing Events  
Regional Offices:  
East, Middle, West Tennessee

ETRO Report  
Taylor Carpenter, MT  
Consultant/Surveyor

East TN Regional Office: April 01-June 30, 2018  
Complaint Investigations: One (in progress)  
Unsuccessful Proficiency Testing: Zero

MTRO Report  
Richard Carroll, MT  
Consultant/Surveyor

Middle TN Regional Office: April 01-June 30, 2018  
Complaint Investigations: Zero  
Unsuccessful Proficiency Testing: Five  
(Acceptable Plans of Correction Submitted to Surveyor)

WTRO Report  
Debbie Haggard, MT  
Consultant/Surveyor

West TN Regional Office: April 01-June 30, 2018  
Complaint Investigations: Zero  
Unsuccessful Proficiency Testing : Two

Motion to accept regional surveyor reports:  
Ms. Kenwright.  
Second: Mr. Johnson.

All surveyor reports accepted as presented.

Board Ratifications  
Initial Facility Applications

Specialties: Cytopathology, Histopathology,  
Oral Pathology

Laboratory Director: Paul DiGiovanni, M.D.  
Anatomic/Clinical Pathology  
Cytopathology

Surveyor: Susan Wilson, MT Consultant I/MTRO

Recuse: Ms. Walton, Mr. Johnson.  
Gavel passed to: Ms. Kenwright for this discussion.

Motion: Dr. Calarco.  
Second: Ms. Dolsen.  
License Approved.

Associated Pathologists, LLC  
d.b.a  
Pathgroup StoneCrest Medical Center  
Pathology Laboratory  
200 StoneCrest Parkway  
Smyrna, TN 37167

Specialties: Oral Pathology, and Cytopathology

Laboratory Director: Sean Silvernagel, M.D.  
Anatomic/Clinical Pathology

Surveyor: Susan Wilson, MT Consultant I/MTRO

Recuse: Ms. Walton, Mr. Johnson.  
Gavel passed to Ms. Kenwright for this discussion.

Motion: Ms. Dolsen.  
Second: Dr. Calarco.  
License approved.

Associated Pathologist, LLC  
d.b.a  
Pathgroup Williamson Medical Center  
Pathology Laboratory  
4321 Carothers Parkway  
Franklin, TN 37067

Specialties: Histopathology, Oral Pathology,  
Cytopathology  
Laboratory Director: Frances L. Cates, M.D.  
Anatomic/Clinical Pathology

Surveyors: Susan Wilson, MT Consultant I/MTRO

Recuse: Ms. Walton, Mr. Johnson.  
Gavel passed to Ms. Kenwright for discussion.

Motion: Dr. Calarco.  
Second: Dr. Davis.  
Licensed Approved.

Associated Pathologists, LLC  
d/b/a  
Pathgroup Sumner Reg. Med. Center  
Pathology Laboratory  
565 Hartsville Pike  
Gallatin, TN 37066

Specialties: Histopathology, Oral Pathology,  
Cytopathology  
Medical Laboratory Director: Julie Lemmon, M.D.  
Anatomic/Clinical  
Pathology  
Surveyor: Susan Wilson, MT Consultant I, MTRO

Recuse: Ms. Walton, Mr. Johnson.  
Gavel passed to Ms. Kenwright for discussion.

Motion: Dr. Calarco.  
Second. Dr. Davis  
License approved.

LeBonheur Children's Hospital  
Anatomic Pathology Laboratory  
50 North Dunlap  
Memphis, TN 38103

Specialties: Histopathology and Frozen Sections

Laboratory Director: Ali Saad, M.D.  
Anatomic Pathology  
Neuropathology  
Pediatric Pathology

Surveyor: Debbie Haggard, Consultant I/Surveyor WTRO

Gavel returned to Ms. Walton, Board Chair

Motion to approve: Mr. Johnson.  
Second: Ms. Kenwright.  
License granted.

BioLife Plasma Services, L.P.  
8015 Bellevue Parkway  
Cordova, TN 38016

Specialties: Spun Hematocrit & Total Serum Protein

Laboratory Director: Charolette Jackson, M.D.  
Physician

Surveyor: Debbie Haggard, Consultant I/Surveyor WTRO

Motion to approve: Ms. Jolly.  
Second: Ms. Cox.  
License approved.

NeoGenomics Laboratories, Inc.  
d/b/a  
NeoGenomics Hampton Ave.  
3604 Hampton Avenue  
Nashville, TN 37215

Specialties: Clinical Cytogenetics  
Laboratory Director: James C. Mixon, M.D.  
Anatomic/Clinical Pathology

Surveyor: Richard Carroll, Consultant II/Surveyor MTRO

Motion to approve: Mr. Johnson.  
Second: Dr. Parham.  
License approved.

IntegralLabs MDG Incorporated Laboratory  
136-A Industrial Park Road  
Piney Flats, TN 37686-4413

Facility was granted certification by the College of American Pathologists, CAP #8763105 after an on-site review on May 22, 2018 in the category of Esoteric Toxicology.

Certification is for two years until renewal is required. Board members acknowledged this required certification and granted this issuance of the license.

Motion to accept the CAP accreditation for this esoteric toxicology laboratory.

Motion: Dr. Davis.  
Second: Ms. Kenwright.

Statement of Next Meeting:

The next meeting will be October 18, 2018.

The beginning time is scheduled for 9 AM CDT in the Iris Conference Room, Ground Floor, Metro Center Complex 665 Mainstream Drive Nashville, TN.

Adjournment:

With no further business to discuss, the meeting adjourned 11:25 am CDT.

Motion to adjourn: Ms. Kenwright.  
Second: Dr. Calarco.

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Patti Walton, MT  
Board Chair

Date